IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	**US 5,674,860**
Issued:	**October 7, 1997**
To:	**Christer Carl Gustav Carling; Jan William Trofast**
For:	**Combination of a Bronchodilator and a Steroidal Anti-Inflammatory Drug for the Treatment of Respiratory Disorders**

CERTIFICATE OF EFS-WEB TRANSMISSION

I hereby certify that this paper is being transmitted via the Electronic Filing System to the U.S. Patent and Trademark Office on the date indicated below.

/John M. Genova/	32,224
Signature	Reg. No.
John M. Genova	24 June 2011
Attorney's Name	Date

HATCH-WAXMAN PTE
Commissioner for Patents
Alexandria, VA 22313-1450

REQUEST TO CORRECT USPTO RECORD

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Sir:

On September 19, 2006, AstraZeneca AB ("Applicant") filed an application for patent term extension ("PTE Application") under 35 U.S.C. §156 with the USPTO to extend the term of U.S. Patent No. 5,674,860 (the "'860 patent"). The '860 patent claims the approved product Symbicort® Inhalation Aerosol, having the active ingredients formoterol fumarate dehydrate and budesonide, and methods of using the approved product. The '860 patent is still in force and has an expiration date of October 7, 2014.

In a Final Determination dated June 13, 2008, the USPTO alleged that the PTE Application was not timely filed. Specifically, the USPTO applied a calendar day interpretation to 37 C.F.R. §156(d)(1) and concluded that the 60 day period for submitting the PTE Application began on the day of FDA approval, i.e., July 21, 2006, and ended 60 days thereafter on September 18, 2006 which, according to the USPTO, made the submission of the PTE Application on September 19, 2006, not timely within the meaning of §156(d)(1).

The Final Determination provided for a single request for reconsideration. On December 16, 2008, Applicant filed a timely Request for Reconsideration. Since then, the USPTO's grounds for dismissing the PTE Application as being untimely under 35 U.S.C. §156(d)(1) has been held to be incorrect by the district court in The Medicines Company v. Kappos, 731 F. Supp. 2d 470 (E.D. Va. 2010). Therefore, the USPTO is respectfully requested to correct the record regarding the determination of the timeliness of the PTE Application in view of The Medicines Company.

Specifically, SYMBICORT was approved by FDA on July 21, 2006. Attached is a copy of the approval letter, including the electronic signature page showing that FDA's transmission of the approval letter occurred after the close of the agency business day on July 21, 2006, at **4:36 PM**. Therefore, in accordance with The Medicines Company, Applicant's period to file the PTE Application did not begin to run until the first business day following the FDA's after-hours transmission. The Medicines Company v. Kappos, 731 F. Supp. 2d 470, _____ (E.D. Va. 2010). July 21, 2006 was a Friday. The next business day was Monday, July 24, 2006. If the first day of the 60 day period set forth in 35 U.S.C. §156(d)(1) was July 24, 2006, then the 60

day period ended on September 21, 2006, thus rendering the submission of the PTE Application on September 19, 2006, timely within the meaning of §156(d)(1).

Authorization is given to charge the any required fee in connection with this communication, to Deposit Account No. 23-1703.

Respectfully submitted,

Dated: 24 June 2011

/Leslie Morioka/
Leslie Morioka
Reg. No. 40,304

Attorney for Applicant

WHITE & CASE LLP
1155 Avenue of the Americas
New York, New York 10036
Tel.: (212) 819-8200
Fax: (212) 354-8113
lmorioka@whitecase.com

Attachment: Copy of Symbicort Approval Letter

ATTACHMENT

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-929

AstraZeneca Pharmaceuticals
1800 Concord Pike
PO Box 8355
Wilmington, DE 19803-8355

Attention: Mark DeSiato
Director, Regulatory Affairs

Dear Mr. DeSiato:

Please refer to your new drug application (NDA) dated September 23, 2005, received September 23, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SYMBICORT® (budesonide/formoterol fumarate dihydrate) Inhalation Aerosol.

We acknowledge receipt of your submissions dated October 21, November 2, 8, and 29, and December 8, 15 (2), 19, and 27, 2005, and January 19, and 30, March 16 (2) and 17 (2), April 11, 13, 19, 26, and 27, May 9, 10, 15 (2), and 31, June 1, 14, 16, and 27, and July 11, 12, 17, 19, and 20, 2006.

This new drug application provides for the use of SYMBICORT® for the long term maintenance treatment of asthma in patients 12 years of age and older.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert [copy enclosed] and Medication Guide[copy enclosed] submitted July 20, 2006, the immediate container label submitted July 11, 2006, and the foil, shield, and carton label submitted July 20, 2006). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-929**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies in patients 6 to less than 12 years of age until December

31, 2007. We are waiving the pediatric study requirement for pediatric patients ages zero to less than 6 years of age.

We remind you of your post-approval Chemistry, Manufacturing, and Controls agreements as listed in your amendment dated July 12, 2006.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Colette Jackson, Regulatory Project Manager, at (301) 796-1230.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, MD, Ph.D.
Director
Division of Pulmonary and Allergy Products
Office of Drug Evaluation II
Center For Drug Evaluation and Research

Enclosure: Package Insert and Medication Guide.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Badrul Chowdhury
7/21/2006 04:36:00 PM